DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 4, 2014

Medtronic Sofamor Danek USA, Incorporated
Ms. Kristi Frisch
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K141632
Trade/Device Name: ZEVO™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 16, 2014
Received: October 17, 2014

Dear Ms. Frisch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141632

Device Name
ZEVO™ Anterior Cervical Plate System

Indications for Use *(Describe)*

The ZEVO™ Anterior Cervical Plate System is intended for anterior interbody screw fixation from C2 to T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis, 5) pseudoathrosis, and/or 6) failed previous fusions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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ZEVO™ Anterior Cervical Plate System
510(k) Summary
December, 2014

I.	**Company:**	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, TN 38132 (901) 396-3133
II.	**Contact:**	Kristi Frisch Senior Regulatory Affairs Specialist
III.	**Proprietary Trade Name:**	ZEVO™ Anterior Cervical Plate System
IV.	**Common Name:**	Spinal Intervertebral Body Fixation Appliance
V.	**Classification Name:**	21 CFR 888.3060 - Spinal Intervertebral Body Fixation Orthosis
	Classification:	Class II
	Product Codes:	KWQ

VI. Product Description:

The ZEVO™ Anterior Cervical Plate System consists of temporary implants (plates and bone screws) intended for anterior screw fixation of the cervical spine during the development of a cervical spinal fusion. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. The device is intended for the anterior screw fixation from C2- T1 in the cervical spine.

The ZEVO™ Anterior Cervical Plate System implants are available in a broad range of size offerings, and are supplied in both sterile and non-sterile form. The implant components are made from titanium alloy, with plates having subcomponents manufacturing from nitinol (NiTi).

VII. Indications for Use:

The ZEVO™ Anterior Cervical Plate System is intended for anterior interbody screw fixation from C2 to T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis, 5) pseudoathrosis, and/or 6) failed previous fusions.

VIII. Summary of Technological Characteristics

The subject ZEVO™ Anterior Cervical Plate System components have the same fundamental scientific technology as the predicate Cervical Spine Locking Plate (CSLP), ATLANTIS® Anterior Cervical System and ZEPHIR® Anterior Cervical System devices. The subject devices are manufactured from the same titanium alloy and nitinol material as the predicate ATLANTIS® devices. The predicate and subject devices are also anterior screw fixation devices where fixation is provided by bone screws inserted into the vertebral body of the cervical spine.

IX. Identification of Legally Marketed Predicate Devices Used to Claim Substantial Equivalence

The subject plate and bone screws are substantially equivalent to the predicates:

Primary Predicate:

- Anterior Cervical Spine Locking Plate (CSLP) System, (K030866, SE 04/18/2003) [SYNTHES® Spine]

Additional predicates:

- ATLANTIS® Anterior Cervical Plate System (K130640, SE 06/04/2013; K081038, SE 08/15/2008) [Medtronic]
- ZEPHIR® Anterior Cervical System (K030327, SE 02/26/2003; K994239, SE 06/19/2000) [Medtronic]

To the best of Medtronic's knowledge, none of the predicates listed here have been subject to a design-related recall.

X. Brief Discussion of the Non-Clinical Tests Submitted

The subject ZEVO™ Anterior Cervical Plate devices were tested in accordance to ASTM F1717-13 "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model" and ASTM F2129-08 "Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices." The subject device met the pre-determined acceptance criteria for all tests. The test results are provided to demonstrate that the subject devices are substantially equivalent to the predicate devices.

XI. Conclusions Drawn from the Non-Clinical Tests

Based on the non-clinical test results and additional supporting documentation provided in this pre-market notification, the subject devices demonstrated substantial equivalence to the listed predicate devices.